

REMARKS

Reconsideration of this application is respectfully requested.

I. Status of the Claims

Claim 1 has been amended to incorporate the limitation of claim 2 that the topical composition has a pH of from about 3.5 to about 8. Claims 1 and 14 have been amended for clarification. Claim 2 has been canceled without prejudice. No new matter has been added.

Claims 1 and 3-19 are pending. Because claims 11-13 have been withdrawn from consideration, only claims 1, 3-10, and 14-19 are at issue.

II. Claim Rejections under 35 U.S.C. § 112

Claims 1-10 and 14-19 have been rejected as indefinite. According to the Examiner, the phrase “an effective amount of (a) L-carnitine, an acyl L-carnitine, a salt thereof, or a mixture thereof.” is ambiguous as to whether both L-carnitine and its acyl derivative are required in the composition and unclear as to which carnitine “a salt thereof” refers.

Claims 1 and 14 have been amended to clarify that the composition comprises “at least one compound selected from (i) L-carnitine, (ii) an acyl L-carnitine, (iii) a salt of L-carnitine, and (iv) a salt of an acyl L-carnitine.”

Applicants submit that the amended claims are definite and request that the rejection be withdrawn.

III. Anticipation Rejection

Claim 1 has been rejected as anticipated by Paul (U.S. Patent No. 6,149,924). The Examiner contends that Paul discloses topical compositions comprising L-carnitine and a hydroxy acid, such as glycolic acid.

Without conceding the validity of this rejection, claim 1 has been amended to incorporate the limitation of claim 2 that “the topical composition has a pH of from about 3.5 to about 8.” Paul fails to teach or suggest any particular pH range for its compositions. The sole composition that is explicitly disclosed (Table A, col. 22) recites only generic ingredients (e.g., “vitamins”, “emollients”, and “preservatives”), the only specifically disclosed compound being deionized water. Therefore, there is not even an implicit disclosure of a pH for this composition. Accordingly, Paul fails to anticipate claim 1 as amended, and applicants respectfully request that the rejection be withdrawn.

IV. Obviousness Rejection

Claims 1-9 and 14-16 have been rejected as obvious over Paul in view of Cavazza et al. (EP 0631779 A1), Johnsen et al. (U.S. Patent No. 3,683,939), Vromen (U.S. Patent No. 6,416,769), Yu et al. (U.S. Patent No. 5,589,505), and Deckner et al. (U.S. Patent No. 5,968,528). According to the Examiner, the cited secondary references disclose the claimed pH ranges and the inclusion of various components, such as proteolytic enzymes, skin bleaching agents, and skin lighteners. Specifically, the Examiner contends that Johnsen teaches that pH for cosmetics is favorable in the range of 5.5 to 7 and that Deckner teaches a pH of between 5 and 8 for compositions containing carnitine and hydroxy acids. Office Action at page 3, last paragraph.

As discussed above, Paul does not disclose or suggest any particular pH for its compositions.

Cavazza discloses esters of L-carnitine and acyl L-carnitine with hydroxy acids. See abstract. These are completely different from compositions comprising L-carnitine and/or acyl-L-carnitine and hydroxy acids. Since it is not possible to prepare the esters of Cavazza by simply mixing and reacting L-carnitine and/or acyl L-carnitine and hydroxy acids, Cavazza is not relevant to the present invention. (In fact, Cavazza discloses a 4-step process for preparing the esters which uses different starting materials. See, for example, Example 1 of Cavazza.)

Johnsen discloses a process for preparing a non-gelling proteinaceous composition that is useful in hair care products. *See* col. 1, line, 65 to col. 2, line 3; col. 3, line 49 to col. 4, line 68. The pH of the concentrated composition following ion exchange treatment is adjusted, if necessary, to be within a range of 4.5 to 7. *See* col. 5, lines 1-45 of Johnsen. The composition disclosed by Johnsen does not contain L-carnitine, hydroxy acids, or skin lighteners. Johnsen fails to teach or suggest that this pH range for a composition specifically used in hair care products is desirable for compositions for topical application to the skin.

In the Office Action, the Examiner states that Yu "adequately state that it is old in the art to add various materials to cosmetic compositions." *See* page 3 of the Office Action. Applicants respectfully request clarification as to the relevance of this overly general (and therefore irrelevant) statement which appears to be based on the collection of laundry lists of materials in columns 2-6 and 18-19 in Yu.

Deckner discloses skin care compositions containing a vitamin B₃ compound. None of the examples provided contains either a hydroxy acid or carnitine. Deckner mentions "carnitine" in a long list of 'thickening and gelling agents'. *See* col. 24, lines 15-22. A person skilled in the art would recognize that the reference to carnitine is an obvious error because carnitine - in contrast to all other members of the list - has no thickening or gelling properties. Carnitine is a water-soluble quaternary amine. *See* L-Carnitine, PDR*Health*, available at http://www.pdrhealth.com/drug_info/-nmdrugprofiles/nutsupdrugs/lca_0060.shtml. Moreover, Deckner, like Yu, has a substantial proportion of its specification made up of a compilation of "laundry lists." The Examiner has impermissibly used hindsight to assemble bits and pieces from various laundry lists of Deckner to support this rejection.

None of the cited references teach or suggest the pH range of the topical composition of the presently claimed invention. The obviousness analysis requires "determin[ing] whether there was an apparent reason to combine the known elements in the fashion claimed . . . To facilitate review, this analysis should be made explicit." *KSR*, 550 U.S. ___, slip op. at 14. The references

cited by the Examiner do not provide the requisite reason to provide the claimed composition in the recited pH range.

For the above reasons, Applicants submit that claims 1, 3-9, and 14-19 are not obvious and respectfully request that the rejection be withdrawn.

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. If there are any remaining issues that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: August 27, 2007

Respectfully submitted,

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